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SURGICAL INSTRUMENT SERVICE COMPANY, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff, vs. INTUITIVE SURGICAL, INC., Defendant.	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **PLAINTIFF/COUNTERCLAIM DEFENDANT SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S ANSWER TO DEFENDANT/COUNTERCLAIM PLAINTIFF'S COUNTERCLAIMS** Complaint Filed: May 10, 2021

Plaintiff/Counterclaim Defendant Surgical Instrument Service Company, Inc. by and through its undersigned counsel, hereby answers the Counterclaims filed by Intuitive Surgical, Inc. as follows:

INTRODUCTION

1. This lawsuit concerns SIS's misinformation campaign to deceive Intuitive customers into believing that the unauthorized modification and remanufacturing of Intuitive's EndoWrist surgical instruments ("EndoWrists") facilitated by SIS is safe, cost-effective, actually conducted by SIS and consistent with both EndoWrists' design specifications and FDA clearances. In reality, the service marketed by SIS as EndoWrist "repair" is none of those things. To the contrary, the "repair" involves another party breaking into EndoWrists and inserting an unauthorized circuit board called the "Interceptor" to override the instruments' safe, prescribed and FDA-cleared use limits. The resulting inferior and unlawful products—still bearing Intuitive's trademarks—carry significant risk not only to Intuitive customers but also to the patients on whom they are used to operate.

ANSWER: SIS denies the allegations.

2. The result of decades of investment and innovation, Intuitive offers surgical systems for use in conducting minimally invasive procedures, including the highly touted da Vinci Surgical System ("da Vinci") and its related instruments and accessories. Intuitive's multi-functional instruments with EndoWrist technology feature wristed joints for natural dexterity, giving surgeons an expanded range of motion and increased precision.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

3. Consistent with industry standards and best practices, and as required by the FDA, Intuitive has conducted rigorous testing and identified maximum use limits for EndoWrists. The maximum use limits, built into the EndoWrists, ensures that instruments perform safely and reliably. Once the

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limit is reached, the instrument will no longer be operational, requiring that it be replaced to avoid putting patients at risk.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

4. EndoWrists are cleared by the FDA to be marketed and sold pursuant to the premarket clearance process set forth in Section 510(k) of the Food, Drug, and Cosmetic Act. The 510(k) process required Intuitive to submit to the FDA extensive data and testing results validating the safety and dependability of EndoWrists within the prescribed use limits. FDA cleared EndoWrists as limited use or "resposable" instruments with use limits, and any modification of EndoWrists by a third party to increase the use limits requires a new 510(k) clearance. SIS did not seek—and the FDA did not provide—510(k) clearance for EndoWrists that are modified so that they could be used ***beyond*** the number of uses that had been validated as safe and reliable.

ANSWER: SIS admits that it did not seek 510(k) clearance for modified EndoWrists but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

5. In light of safety and reliability concerns, among others, customers agree in their contracts with Intuitive that (i) they will not use Intuitive instruments after the maximum use limit is reached, and (ii) unauthorized parties are prohibited from modifying or altering the instruments.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

6. Despite being well aware of the prohibitions in Intuitive's contracts, SIS has solicited Intuitive customers to retain it to "repair" EndoWrists and override their use counters. Unbeknownst to the customers, once retained, SIS sends instruments to a third party, Rebotix Repair LLC ("Rebotix"), that breaks into the EndoWrists and implants the unauthorized "Interceptor" circuit board. This unauthorized process results in "manufactured" or "remanufactured" instruments that include new

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materials inconsistent with the instruments' design and functional requirements. These added materials have never been tested or validated by Intuitive and, upon information and belief, have not been properly tested or validated by Rebotix or SIS in accordance with regulatory requirements. Rebotix then returns the adulterated instruments back to SIS, which in turn sends them back to its customers for use in surgical procedures.

ANSWER: SIS admits that it has solicited Intuitive customers to retain it to refurbish EndoWrists. SIS otherwise denies the allegations.

7. SIS does not inform Intuitive customers of the true nature of SIS's (and Rebotix's) unauthorized operations, let alone the substantial medical, financial and legal risks that customers face if they secure EndoWrist "repairs" through SIS.

ANSWER: SIS denies the allegations.

8. SIS's success thus depends on its ability to deceive Intuitive customers. To that end, marketing materials and communications disseminated by SIS are rife with false and misleading statements, all as part of a coordinated effort to bolster and legitimize unlawful EndoWrist remanufacturing operations.

ANSWER: SIS denies the allegations.

9. SIS's willfully deceptive marketing claims are of several stripes. Many specifically concern the nature of the offered service, deceiving customers into believing that EndoWrist use limits can be extended in a way that is safe, effective and reliable and that conforms to regulatory requirements.

ANSWER: SIS denies the allegations.

For example:

a. SIS states that it is "repairing" EndoWrists and does not describe the actual, substantial modifications being made to the instruments. *See, e.g.,* Ex. 1, Ex. 2, Ex. 3.

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Contrary to a mere "repair," the Interceptor process is not a tune-up or calibration, but rather ***changes*** EndoWrists in fundamental (and risky) ways.

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS otherwise denies the allegations.

b. SIS purports to offer a "complete evaluation, repair, and test" of EndoWrists, further conveying a false message that the instruments are broken or defective when they reach their use limit. *See, e.g.,* Ex. 2. But SIS knows that the use limits are a ***feature,*** not a bug, of EndoWrists because they ensure proper and safe operation.

ANSWER: SIS admits that it offers a "complete evaluation, repair, and test" of EndoWrists but otherwise denies the allegations.

c. SIS claims that serviced EndoWrists will "meet the quality and functional requirements of a new device" (*see, e.g.,* Ex. 3), but SIS does not have access to Intuitive's design history and other internal files to identify the "quality and functional requirements" of new EndoWrists.

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS admits that it does not have access to Intuitive's design history and other internal files. SIS further denies that it does not have sufficient information of quality and functional requirements of new EndoWrists.

d. SIS similarly claims that a "repaired" EndoWrist "is an original da Vinci manufactured device that has been repaired to original specifications" (*see, e.g.,* Ex. 1), but SIS does not know the instruments' "original specifications" and is aware that overriding prescribed use limits would be inconsistent with any such specifications.

ANSWER: SIS admits that it claims that a refurbished EndoWrists "is an original da Vinci manufactured device that has been repaired to original specifications" but otherwise denies the allegations.

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e. SIS misrepresents Intuitive's justifications for use limits and Intuitive's testing and safety protocols, as well as the safety of SIS's service.

ANSWER: SIS denies the allegations.

10. The foregoing deceptive messages are compounded by SIS falsely representing to customers that ***it*** performs the "repairs" and has tested the reliability of the use-extended EndoWrists. SIS thus leverages its brand and purported long history of experience servicing surgical instruments while obscuring the fact that EndoWrist "repair" is actually done by Rebotix. *See, e.g.,* Ex. 2, Ex. 3. In fact, SIS has never conducted a repair of an EndoWrist for a customer or conducted any testing of the "repaired" instruments.

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS otherwise denies the allegations.

11. Based on the false premise that the service is merely a "repair" of EndoWrists, SIS also misinforms customers that "repaired" instruments do not require 510(k) premarket clearance by the FDA. *See, e.g.,* Ex. 3. Relatedly, SIS misinforms customers that the "repair" service does not change the intended use, method of use, functionality or performance of EndoWrists. Both sets of representations are not true, and SIS made the statements either with knowledge of their falsity or, at minimum, without conducting any independent or meaningful investigation as to whether clearance was required. SIS has further misinformed customers about the nature and scope of Intuitive's 510(k) clearance for EndoWrists, such as misinforming customers that the FDA only regulates single-use surgical instruments.

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS otherwise denies the allegations.

12. Yet another category of SIS's false advertising is its touting and purported validation of cost savings for customers who use the "repair" service instead of purchasing new EndoWrists. For example, SIS advertises that its service offers significant savings for customers. Lacking a

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legitimate basis to make such claims, SIS fails to inform customers and/or affirmatively misrepresents the financial and legal consequences for customers that use the unauthorized services, such as the voiding of customers' warranties and jeopardizing of their service contracts with Intuitive.

ANSWER: SIS admits that it advertises that its service offers significant savings for customers but otherwise denies the allegations.

13. SIS also has leveled false accusations against Intuitive, including a baseless and inflammatory charge that the use limitations built into EndoWrists are "arbitrary." *See, e.g.,* Ex. 2. SIS knows, or should know, however, that the use limits are critical for patient safety, designed in compliance with FDA regulations, requirements and publications, consistent with applicable industry standards as well as EndoWrist labeling and amply supported and validated by scientific testing.

ANSWER: SIS admits that its "Summary of Quality and Reliability Measures" states that "The da Vinci® S/Si Instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures." SIS otherwise denies the allegations.

14. SIS's communications similarly have falsely suggested that the "repair" service was authorized by, approved by or affiliated with Intuitive, including through misleading references to Intuitive trademarks and describing SIS as an "authorized" EndoWrist "service" company.

ANSWER: SIS denies the allegations.

15. SIS's deceptive practices are not strictly limited to its false advertising. Despite being qualitatively different from and inferior to originally manufactured EndoWrists, "repaired" instruments with the unauthorized "Interceptor" still bear Intuitive's trademarks. As such, surgeons and others encountering the "repaired" EndoWrists are led to believe that those instruments still are genuine Intuitive products. That deception is furthered by SIS's communications stating that "[a] repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications." Ex. 1.

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ANSWER: SIS admits that its refurbished EndoWrists bear Intuitive's trademarks. SIS further admits that its "da Vinci® EndoWrist® Repairs" document states that "[a] repaired EndoWrist® is not an alternative or replacement device. It is an original da Vinci® manufactured device that has been repaired to original specifications." SIS otherwise denies the allegations.

16. All of the foregoing deceptive practices are part and parcel of SIS's false pitch that: (i) it can and does "repair" EndoWrists in a manner that saves large sums of money without any downside or risk; (ii) such "repair" service is authorized by Intuitive and does not require FDA 510(k) clearance; and (iii) Intuitive's safety and other requirements need not be adhered to or trusted. The dangers of such an inaccurate campaign to customers and their patients are self-evident, and SIS bears liability for these reckless communications.

ANSWER: SIS denies the allegations.

PARTIES

17. Intuitive is a Delaware corporation with its principal place of business at 1266 Kifer Road, Sunnyvale, California. Among other services, Intuitive manufactures and sells surgical systems, along with related instruments and accessories, to hospitals and surgical centers world-wide.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

18. Surgical Instrument Service Company, Inc. is an Illinois corporation with a principal place of business at 151 N. Brandon Drive, Glendale Heights, Illinois. SIS purports to offer repair and replacement services for Intuitive's EndoWrists, including but not limited to customers in California.

ANSWER: SIS admits the allegations.

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JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over Intuitive's federal claims under 28 U.S.C. § 1331 and § 1332. The federal claims arise under the Lanham Act, 15 U.S.C. § 1125. This Court has supplemental subject matter jurisdiction over Intuitive's state-law claims under 28 U.S.C. § 1367(a).

ANSWER: SIS admits the allegations.

20. This Court has personal jurisdiction over SIS, and venue is proper in the Northern District of California pursuant to 28 U.S.C. § 1391(b) and (c), as SIS has appeared in this action and initiated this action by filing claims against Intuitive in this District.

ANSWER: SIS admits the allegations.

GENERAL ALLEGATIONS

I. Intuitive's da Vinci Surgical Systems and EndoWrist Precision Instruments

21. Intuitive designs, manufactures and markets da Vincis and related instruments and accessories, which have become widely known as an advanced generation of surgery. Da Vincis combine the benefits of minimally-invasive surgery for patients with the ease of use, precision and dexterity of open surgery for surgeons.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

22. A da Vinci consists of a surgeon's console, a patient-side cart and a high-performance vision system. Da Vinci technology translates a surgeon's natural hand movements, which are performed on instrument controls at the console, into corresponding micro-movements of instruments positioned inside the patient through small incisions or ports. The da Vinci provides operating surgeons with intuitive control, range of motion, fine tissue manipulation capability and three-dimensional, high-definition vision, while simultaneously allowing surgeons to work through small ports.

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

23. Through its extensive efforts and investments in research and development, as well as through strategic alliances with other medical and technology companies, Intuitive has developed and commercialized four generational platforms of da Vinci and continues to innovate in order to help surgeons improve surgical outcomes.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

24. In addition to the primary surgical platforms, Intuitive develops, manufactures and sells compatible instruments and accessories customized for various surgical procedures, such as forceps, scissors, electrocautery tools and scalpels.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

25. Most of these instruments incorporate EndoWrist technology, which feature wristed joints for natural dexterity. Inspired by the human hand, EndoWrists enable surgeons to orient the instruments carefully relative to the tissue and suture with precision, just as they can in open surgery. EndoWrists' internal cables provide maximum responsiveness, allowing for rapid and precise suturing, dissection and tissue manipulation.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

26. Because of the innovations and benefits that they provide, da Vincis and EndoWrists have successfully enabled surgeons to perform a wide range of surgical procedures across a variety of specialties. That success has made Intuitive's offerings a highly desirable, competitive alternative to other surgical modalities, such as open and laparoscopic surgery.

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

II. Use Limits Ensure EndoWrists Meet The Highest Quality and Safety Standards and Are Compliant With Applicable State, Federal and International Requirements and Guidelines

27. Intuitive goes to great lengths to ensure that its various products are safe, effective and reliable. Through its dedicated engineers, Intuitive subjects its products to extensive testing to ensure its products are safe, reliable and efficacious.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

28. Among other steps taken to ensure that EndoWrists meet exacting performance specifications, most are designed with a use life of a defined number of procedures. A programmed memory chip inside each such instrument performs several functions that help determine how the da Vinci and EndoWrists work together, including by not allowing instruments to be used for more than the prescribed and appropriate number of procedures.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

29. The use limits for EndoWrists are determined through a rigorous process involving substantial scientific testing and analysis. For example, instruments are subject to testing protocols that: (i) expose them to mechanical and electrical stress representative of intended use, taking into account procedure variances; and (ii) put them through typical installation, cleaning and sterilization cycles to simulate real-life uses in the surgical field as nearly as possible. Analyzing the data from its various tests, Intuitive also applies complex statistical models to identify risks and confirm the number of times that each instrument can safely and reliably be used.

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

30. Intuitive's incorporation of use limits into EndoWrists and other products is important as a best practice, critical to regulatory compliance and consistent with 510(k) clearance for previous iterations of the EndoWrist.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

31. Many of Intuitive's products and operations are subject to regulation in each of the countries and regions where Intuitive markets and sells products. Intuitive therefore is careful to stay up to date on the requirements of a large and growing body of international standards, which govern the design, manufacture, sourcing, testing, certification, packaging, installation, use and disposal of Intuitive products.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

32. In the United States, for example, Intuitive submits many of its systems, instruments and accessories to the U.S. Food and Drug Administration ("FDA") for premarket clearance.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

33. Under the Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide a reasonable assurance of safety and effectiveness. Intuitive's current products, including EndoWrists, are Class II medical devices, which are subject to general controls and typically require premarket demonstration of adherence

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to FDA performance standards or other special controls in order to obtain clearance. Premarket review and clearance are accomplished through the 510(k) premarket notification process.

ANSWER: SIS admits the allegations.

34. Critically, through its regulations, requirements and publications, the FDA mandates that in order for 510(k) clearance to be issued, the EndoWrist's maximum use limits must be determined and disclosed. Accordingly, when Intuitive builds use limits into EndoWrists, it is both adhering to best practices and taking the steps necessary to comply with federal (and other) requirements. It is further complying with FDA's prior 510(k) clearances of EndoWrists as limited use devices with use limits built in.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

35. Even after a medical device like an EndoWrist receives initial 510(k) clearance from the FDA, any ***modification*** to the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a ***new*** 510(k) clearance, or could even require a premarket application ("PMA") approval. *See* 21 C.F.R. § 807.81(a)(3). The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) clearance or PMA in the first instance, but the FDA may review any such determination. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular modification, the FDA may retroactively require the manufacturer to do so, and under certain circumstances may require the manufacturer to cease marketing and/or recall the modified device until clearance or approval is obtained.

ANSWER: SIS admits that 21 C.F.R. § 807.81(a)(3) states that "(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the

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following criteria: (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

> (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
>
> (ii) A major change or modification in the intended use of the device."

SIS admits that FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) clearance or PMA in the first instance, but the FDA may review any such determination. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular modification, the FDA may retroactively require the manufacturer to do so, and under certain circumstances may require the manufacturer to cease marketing and/or recall the modified device until clearance or approval is obtained. SIS otherwise denies the allegations.

36. The FDA recently stated to Intuitive that extending the number of lives on EndoWrists with use limits is inconsistent with the cleared labels and requires a separate 510(k) submission that includes "[b]ench validation data or scientific justification" in order "to demonstrate that the instruments maintain adequate performance (as defined in your existing instrument validation protocols) after the maximum number of uses and reprocessing cycles." Exs. 6, 7.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

37. Any company that ***manufactures*** a non-exempt device, including a finished device component for sale to an end user, must obtain 510(k) clearance. *See* 21 U.S.C, §§ 321(h); 807.3(d)(3); 807.81(a)(2); 807.20(a), (a)(6).

ANSWER: SIS denies the allegations.

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38. Further, any company that ***remanufactures*** devices or instruments as that term is defined by the FDA must obtain 510(k) clearance. *See* 21 C.F.R. § 807.81(a)(3). Per FDA regulations, a "remanufacturer" is "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." *See* 21 C.F.R. § 820.3(w).

ANSWER: SIS admits that 21 C.F.R. § 807.81(a)(3) states that each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration for a device that is a device which the person "currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification: (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. (ii) A major change or modification in the intended use of the device." SIS admits that 21 C.F.R. § 820.3(w) states that "[r]emanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." SIS otherwise denies the allegations.

III. Intuitive's Commitment to Product Safety, Quality and Efficacy By Prohibiting Unauthorized Maintenance and Support Services

39. Given the surgical uses for which Intuitive's products are designed, proper maintenance of those products is essential. Intuitive customers therefore have access to an expansive infrastructure of specialists and engineers around the world who can offer a full complement of round-the-clock support and service for the da Vincis. That infrastructure includes a network of field service engineers across the United States, Europe and Asia, as well as distributors and service providers around the globe with whom Intuitive maintains relationships.

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

40. Intuitive ensures that any in-house technicians or authorized third-party technicians that are part of Intuitive's service and support teams have the specialized training and experience necessary to safely and reliably work on the highly technical da Vincis. This training continues throughout the course of the technicians' careers servicing the da Vinci so that they are fully up-to-date on the technology.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

41. Maintenance or modification of Intuitive devices by unauthorized and/or unqualified individuals, however, could lead to adverse outcomes and carry additional risk to surgical patients and to Intuitive customers that Intuitive would be unable to mitigate. For example: (i) non-validated reprocessing methods, and unknown handling and transit conditions have the potential to damage instruments; (ii) handling and product modification can impact traceability and monitoring of the device by Intuitive, including Intuitive's ability to update customers about important developments like recalls; and (iii) using unauthorized channels for acquisition or maintenance of products may violate a given hospital's or health care facility's internal policies and impact the validity of patient consents.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

42. For these reasons and others, Intuitive carefully restricts who is permitted to perform maintenance and support services on its products and prohibits unauthorized parties from doing so.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

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43. In that regard, Intuitive customers enter into binding Sales, License, and Service Agreements ("SLSA") governing their acquisition and use of Intuitive devices. In those Agreements, the customer unequivocally agrees that, *inter alia,* it "will not, ***nor will Customer permit any third party to, modify,*** disassemble, reverse engineer, ***alter,*** or misuse" the Da Vinci Surgical System or instruments (such as EndoWrist) and accessories. SLSA § 3.4 (emphasis added).

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

44. If a third party does modify, alter, or otherwise manipulate Intuitive devices, thus violating the above contractual provision, "any warranties applicable to the System will become void" and Intuitive may terminate the SLSA immediately upon written notice. *Id.* Relatedly, if a customer "has used the System with surgical instruments or accessories that are not Instruments or Accessories [i.e., those made or approved by Intuitive for use with the System]," then the system warranty "is void with respect to any claims." SLSA §§ 2, 10.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

45. The SLSA also includes an express acknowledgment by Intuitive customers that they may not use instruments after they have exceeded the use limits, or if those instruments have been subject to any servicing or modification not authorized by Intuitive:

> Instruments and Accessories are subject to a limited license to use those instruments and Accessories with, and prepare those Instruments and Accessories for use with, the System. ***Any other use is prohibited,*** whether before or after the Instrument or Accessory's license expiration, ***including repair, refurbishment, or reconditioning not approved by Intuitive. This license expires once an instrument or Accessory is used up to its maximum number of uses*** specified in the Documentation accompanying the Instrument or Accessory. SLSA § 8 (emphasis added); *see also id.* § 3.4 (requiring proper use of the da Vinci system consistent with the attached documentation, including the user manual).

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

IV. SIS's Unauthorized Facilitation of Overriding EndoWrist Use Limits By A Third Party, Rebotix Repair LLC

46. SIS characterizes itself as a medical and surgical device servicing company that has been a "trusted partner for over 50 years." *See* http://sis-usa.com/. In its marketing, SIS asserts that "SIS technicians are among the most highly-skilled and experienced in the industry," with a "majority" that are "pioneers in improved repair techniques." http://sis-usa.com/services/. Central to SIS's branding is not only its purported expertise—e.g., that it can "extend the useful life of your critical instruments"—but also the notion that it is trustworthy. SIS states, for example, that it has "no competing agendas" and "we always speak honestly with our customers." *Id.*

ANSWER: SIS admits that it characterizes itself as a medical and surgical device servicing company that has been a "trusted partner for over 50 years." It further admits that it asserts that "SIS technicians are among the most highly-skilled and experienced in the industry," and that a "majority" that are "pioneers in improved repair techniques." SIS admits that its expertise and trustworthiness are elements of its branding. SIS otherwise denies the allegations.

47. SIS markets its services to customers throughout the United States, including customers in the State of California.

ANSWER: SIS admits that it markets its services to customers throughout the United States, including customers in the State of California.

48. SIS learned of a process by which another party, Rebotix Repair LLC ("Rebotix"), was manufacturing EndoWrists with finished device components (i.e., the Interceptor) and/or remanufacturing EndoWrists in order to override their use limits. Unconcerned with serious safety implications for surgical patients, or legal and financial consequences for Intuitive customers, Rebotix developed its "Interceptor" process to disable memory chips in EndoWrists. That process

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involves breaking into the instruments, discarding original instrument circuit boards, soldering the Intuitive memory chips onto unauthorized circuit boards and installing those adulterated circuit boards back into the instruments. In short, Rebotix inserts its own technology to override a fundamental feature of EndoWrists, significantly changing their intended use and their performance and safety specifications.

ANSWER: SIS admits that it learned that Rebotix Repair LLC could override use limits. SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Rebotix's process and, on that basis, denies the allegations. SIS otherwise denies the allegations.

49. Notwithstanding the fact that Rebotix's modifications of EndoWrists are substantial, and that its activity renders Rebotix a "manufacturer" or "remanufacturer" within the context of applicable FDA regulations (*see supra* ¶¶ 35-38), Rebotix never received 510(k) clearance from the FDA for its operations or for the marketing and sale of EndoWrists with overridden use counters. Upon information and belief, SIS knew that Rebotix never received 510(k) clearance and was aware of Rebotix's prior communications with the FDA in which Rebotix failed to obtain any such clearance.

ANSWER: SIS admits that it knew that Rebotix did not receive FDA clearance for its EndoWrist services. SIS otherwise denies the allegations.

50. Indeed, Rebotix's failure to receive 510(k) clearance for its operations is directly contrary to the FDA's directive to Rebotix that the Interceptor "repair" process ***requires*** 510(k) clearance. For example, in a letter to Rebotix in 2018, the FDA indicated to Rebotix that its Interceptor process required 510(k) clearance. Specifically, the FDA stated, "for the reusable EndoWrist Instruments, if the use-life counter is reset of extended past the number of available use lives, then the device specification are changed." Intuitive's Motion to Stay Exhibit, REBOTIX166917, (ECF No. 46-2). On this basis, the FDA indicated that Rebotix would be "subject to premarket notification (510(k)) requirements." *Id.*

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ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

51. Seeking to piggyback on Intuitive's success and expand its own business, SIS entered into a business relationship with Rebotix whereby SIS effectively functions as a distributor. Upon information and belief, SIS markets and sells EndoWrist "repairs" to hospitals and collects devices from the hospitals to deliver them to Rebotix, which then conducts the "repairs." SIS pays Rebotix a "distributor price" for each "repair" and charges SIS customers a higher retail price for the "repaired" device.

ANSWER: SIS admits that it entered into a business relationship with Rebotix but otherwise denies the allegations.

52. SIS entered into the relationship with Rebotix and has marketed and sold the "repair" service to customers despite being fully aware that EndoWrists should not be used for more than the prescribed and appropriate number of procedures, and that Intuitive's customers agree in their service contracts that unauthorized parties should not service or modify instruments.

ANSWER: SIS admits that it entered into a business relationship with Rebotix and has marketed EndoWrist service to customers but otherwise denies the allegations.

53. SIS also is aware that Rebotix had not obtained 510(k) clearance from the FDA to market or sell the "repaired" EndoWrists.

ANSWER: SIS admits that it is aware that Rebotix had not obtained 510(k) clearance from the FDA but otherwise denies the allegations.

54. SIS has never conducted an EndoWrist "repair" for a customer. Instead, it only provides EndoWrists to Rebotix and then reaps the premium that it charges its customers.

ANSWER: SIS admits that it has never conducted a repair of an EndoWrist but otherwise denies the allegations.

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V. SIS's Deceptive Marketing and Conduct

55. SIS's EndoWrist-related business is supported by a misinformation campaign targeted at Intuitive customers. The overarching goal of the campaign is to persuade EndoWrist purchasers into believing that the "repairs" SIS coordinated are actually provided by SIS, legitimate, cost-effective, safe and without any downside or risk. In reality, SIS's (and Rebotix's) service is none of those things.

ANSWER: SIS denies the allegations.

56. SIS's campaign of deception spans several different kinds of false and misleading marketing claims.

ANSWER: SIS denies the allegations.

57. Much of SIS's efforts at deception concern misrepresenting the nature, efficacy and safety of its service. As set forth above, the Interceptor process overhauls EndoWrists, forcing them to operate beyond their safe, reliable and FDA-cleared use lives. Yet SIS falsely markets the service as safe, effective and reliable, and conceals from the public that the service requires breaking into Intuitive instruments to make modifications such as inserting an unauthorized circuit board.

ANSWER: SIS denies the allegations.

58. For example, SIS markets the service as a "repair" or "complete evaluation, repair, and test" of EndoWrists, inaccurately conveying to customers that the service is simply a tune up or other routine step to bring the instruments back to their original condition. *See* Exs. 1, 2.

ANSWER: SIS admits that it markets the service as a "repair" or "complete evaluation, repair, and test" but otherwise denies the allegations.

59. Suggesting that EndoWrists are "repaired" not only mischaracterizes the nature of SIS's (more accurately, Rebotix's) operations, but further conveys the false message that instruments that have reached their use limits are broken, defective or otherwise in need of fixing. SIS knows, however,

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that there is nothing broken about an EndoWrist that cannot exceed its predetermined use limit; to the contrary, that the instrument can no longer be used is a fully intended—and critically important—safety feature.

ANSWER: SIS denies the allegations.

60. SIS furthers the deception about what the "repair" actually entails by falsely touting that a "repaired" EndoWrist (i) "meet[s] the quality and functional requirements of a new device" (Ex. 3) and (ii) "has been repaired to original specifications" (Ex. 1). These fictions are reiterated even in SIS's Complaint in this litigation. SIS Compl. ¶ 8 ("SIS's services ensure that the inspected or repaired EndoWrists meet all original specifications").

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS admits that it states that a refurbished EndoWrist "has been repaired to original specifications." SIS otherwise denies the allegations.

61. These claims deceive customers in at least two ways. ***First,*** it is not true that the adulterated EndoWrists retain "original specifications" or "meet the quality and functional requirements of a new device." SIS and Rebotix do not have the capability to provide customers with modified EndoWrists equivalent to the quality and functional requirements of new, out-of-the-box, EndoWrists manufactured by Intuitive. At its core, the remanufactured product is qualitatively different from—and does not maintain the original specifications of—an out-of-the-box EndoWrist (e.g., it incorporates the unauthorized "Interceptor" and exceeds the instrument's prescribed use limits, which themselves are specifications for the instruments). ***Second,*** SIS misrepresents that it has taken the steps necessary to sufficiently validate its claim that the "requirements" of a "new device" have been met—e.g., conducting or relying on reliable scientific testing and analysis. SIS plainly had not done so, nor has SIS ever had access to the Intuitive internal files that would specify the "quality and functional requirements" of new EndoWrists.

ANSWER: SIS denies the allegations.

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62. SIS compounds the deceptiveness of the "repair" messaging by falsely conveying to customers that it is ***SIS*** that actually has developed and performs the "complete evaluation, repair and test" of EndoWrists. Seeking to leverage its reputation and "50-year history of performing repairs," SIS does not disclose that SIS does not perform the EndoWrist "repair" itself or did not perform any of the testing that purportedly supports the safety and reliability of the EndoWrist "repair" process. In fact, SIS has utilized ***Rebotix's*** deceptive communications and simply re-branded them as SIS's. *Compare* Ex. 2, *with* Ex. 4; *compare* Ex. 3, *with* Ex. 5.

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS otherwise denies the allegations.

63. Evidence that customers actually have been deceived by the foregoing false messaging already exists on the public record. In a separate federal litigation concerning EndoWrists, a putative class of Intuitive customers have alleged that SIS "has already serviced and repaired EndoWrists." *In re: Da Vinci Surgical Robot Antitrust Litigation,* Case 3:21-cv-03825-VC, ECF No. 52, "Larkin Amended Complaint," at ¶ 124.

ANSWER: SIS denies that customers actually have been deceived by messaging cited on the public record. SIS otherwise denies the allegations because it is without knowledge or information to form a belief as to the truth of the allegations.

64. Certain other deceptive marketing claims by SIS concern the legality and legitimacy of the remanufacturing services.

ANSWER: SIS denies the allegations.

65. To mollify concerns that customers would have about subjecting surgical instruments to unauthorized "repair" services, and further underscore the false message that the service is safe, effective and reliable, SIS falsely informed customers that the EndoWrist services do not require FDA certification or clearance. *See, e.g.,* Ex. 3. But that is not true. As set forth above, any company that ***manufactures*** a non-exempt finished device component for sale to an end user or

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remanufactures devices or instruments—including engaging in any "act to a finished device that significantly changes the finished device's performance or safety specifications, ***or intended use"*** (21 C.F.R. § 807.81(a)(3))—must obtain 510(k) clearance. *See* 21 C.F.R. § 820.3(w) (emphasis added).

ANSWER: SIS denies that Ex. 3 was created, disseminated or otherwise made publicly available by SIS. SIS otherwise denies the allegations.

66. Relatedly, SIS falsely informs customers that its "repair" process does not change the intended use, method of use, functionality or performance of EndoWrists. By inserting the Interceptor to override use limits, SIS changes the intended use of EndoWrists, which requires conformance to the prescribed and FDA-cleared use limits. SIS's "repair" process was also not adequately tested to ensure safe and effective use beyond FDA-cleared limits. Accordingly, the "repair" process results in EndoWrists whose functionality and performance have been significantly changed.

ANSWER: SIS denies the allegations.

67. Upon information and belief, SIS knew all along that 510(k) clearance was required (but had not been obtained). At minimum, SIS did not conduct any independent or meaningful investigation to determine whether additional clearance is necessary.

ANSWER: SIS denies the allegations.

68. Yet another category of SIS's false advertising is its claims that using the "repair" service would result in substantial cost-savings and financial benefits for Intuitive customers. For example, SIS has claimed that it can provide an Intuitive customer with significant savings, and the public record indicates that customers did in fact believe similar claims of savings of as much as 55-70% by using SIS rather than purchasing replacement EndoWrists from Intuitive. *See* Larkin Amended Complaint ¶¶ 7, 155. This, too, is deceptive because SIS has no legitimate basis or support to make such claims.

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ANSWER: SIS admits that it advertises that its EndoWrist services can provide an Intuitive customer with significant savings but otherwise denies the allegations.

69. SIS's marketing and communications also deceive customers by intentionally obscuring and omitting the negative consequences for customers that retain SIS, including that SIS's unauthorized alterations could void customers' warranties. SIS fails to inform customers that its unauthorized services could subject customers to contract and warranty ramifications under their SLSAs with Intuitive by virtue of using unauthorized service technicians.

ANSWER: SIS denies the allegations.

70. SIS also has leveled false accusations against Intuitive and attacked Intuitive's credibility and trustworthiness. For example, SIS baselessly asserts that the EndoWrists' use limits are "arbitrary." *See, e.g.,* Ex. 2. As detailed above (*supra* at ¶¶ 3, 4, 29), nothing could be further from the truth; the use limits were set after rigorous analysis, are determined pursuant to FDA law and regulations and industry standards and are an essential component of ensuring patient health and safety.

ANSWER: SIS admits that its "Summary of Quality and Reliability Measures" states that "The da Vinci® S/Si Instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures." SIS otherwise denies the allegations.

71. Finally, SIS misleads customers into believing that its service is authorized, approved, or endorsed by Intuitive. SIS's marketing materials frequently depict Intuitive's trademarks, including marks protected by incontestable federal registrations such as "EndoWrist" (U.S. Reg. No. 2,591,824) and "da Vinci" (U.S. Reg. No. 2,628,871). In addition, SIS has referred to itself as an "authorized" EndoWrist "service" company.

ANSWER: SIS admits that its refurbished EndoWrists bear Intuitive's trademarks but otherwise denies the allegations.

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72. Even beyond its false advertising, SIS deceives customers by misrepresenting "repaired" instruments as genuine, Intuitive-manufactured EndoWrists. As detailed above, the Interceptor process fundamentally alters EndoWrists, rendering them qualitatively different from, and inferior to, EndoWrists originally manufactured and sold by Intuitive (and cleared by the FDA). Yet the "repaired" instruments appear outwardly identical to Intuitive's EndoWrists and still bear Intuitive's trademarks—including trademarks for which Intuitive holds incontestable federal registrations, such as "EndoWrist" (U.S. Reg. No. 2,591,824) and "Intuitive Surgical" (U.S. Reg. No. 2,364,862). As such, surgeons and other downstream users or recipients of the "repaired" EndoWrists——including anyone who experienced inconsistencies or failures with the adulterated instruments—are likely to confuse the adulterated instruments with Intuitive-manufactured products.

ANSWER: SIS admits that its refurbished EndoWrists appear outwardly identical to Intuitive's EndoWrists and that they bear Intuitive's trademarks but otherwise denies the allegations.

73. SIS's communications furthered this deception by utilizing Intuitive's registered trademarks on its marketing materials and by expressly telling its customers that "[a] repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications." (Ex. 1.)

ANSWER: SIS admits that it represented in Ex. 1 both that "[a] repaired EndoWrist® is not an alternative or replacement device," and that a repaired EndoWrist is "an original da Vinci® manufactured device that has been repaired to original specifications" but otherwise denies the allegations.

VI. Through its Unfair Business Practices, SIS Has Knowingly Interfered With Intuitive's Business and Contractual Relationships With its Customers.

74. As noted above (*supra* at ¶¶ 43-45) Intuitive SLSAs include express acknowledgments by customers that (i) they will not use Intuitive instruments after the maximum use limit is reached; (ii) their licenses to use instruments (such as EndoWrists) expire once maximum use limits are

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reached; and (iii) they will not use unauthorized components or permit third parties to modify or alter the instruments, and doing so will void Intuitive's warranties and permit Intuitive to terminate the service contracts.

ANSWER: SIS denies the allegations because it is without knowledge or information to form a belief as to the truth of the allegations.

75. SIS had knowledge of the SLSAs and the terms thereof, including the foregoing provisions.

ANSWER: SIS denies the allegations.

76. Notwithstanding such knowledge, SIS has induced Intuitive customers to breach the SLSAs to their detriment and utilize SIS's (and, unbeknownst to the customers, Rebotix's) services, resulting in EndoWrist use beyond their intended, prescribed, and FDA-cleared use limits.

ANSWER: SIS denies the allegations.

77. SIS's interference with the relationship between Intuitive and its customers goes beyond facilitating the breach of the SLSA. For example, SIS has sought to disrupt that relationship by misinforming customers that Intuitive is dishonest and engages in unethical or unlawful practices, such as by setting "arbitrary" EndoWrist use limits. SIS further sold a service to customers that required 510(k) clearance under FDA rules and regulations, despite not having such clearance. Thus, SIS's actions are not the reflection of legitimate competition but rather an improper means to induce customers into breaching their contracts with Intuitive.

ANSWER: SIS admits that its "Summary of Quality and Reliability Measures" states that "The da Vinci® S/Si Instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures." SIS otherwise denies the allegations.

VIII. The Substantial and Irreparable Harm to Intuitive and Its Customers

78. SIS's deceptive conduct and interference with Intuitive's contractual relationships has harmed Intuitive and its customers in a number of ways, including, but not limited to, the following:

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ANSWER: SIS denies the allegations.

79. ***First,*** SIS's unlawful conduct has deprived Intuitive of business. For example, customers who would have ordered replacement EndoWrists when it is time to do so are instead turning to SIS's so-called "repair" services.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations that customers who would have ordered replacement EndoWrists from Intuitive when it is time to do so are instead turning to SIS's services and, on that basis, denies the allegations. SIS otherwise denies the allegations.

80. ***Second,*** Intuitive's reputation and goodwill has been damaged by SIS's direct attacks on Intuitive's honesty and integrity. By baselessly asserting that the EndoWrist's use limits are "arbitrary" and financially motivated, SIS tells customers that Intuitive should not be trusted, and that its important guidance on proper instrument use need not be followed.

ANSWER: SIS admits that its "Summary of Quality and Reliability Measures" states that "The da Vinci® S/Si Instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures." SIS otherwise denies the allegations.

81. ***Third,*** to the extent that "repaired" EndoWrists do not function properly during surgery, it jeopardizes the public trust and confidence that Intuitive has inspired among its customers' patients.

ANSWER: SIS denies the allegations.

82. ***Fourth,*** customers themselves have been harmed in numerous ways by SIS's unlawful conduct, including by (i) receiving a qualitatively different and inferior product than that which they had bargained for; (ii) not receiving the cost-savings actually promised by SIS; (iii) having their service contracts and/or warranties with Intuitive voided or otherwise jeopardized; (iv) having their ability

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to raise concerns about adulterated (and misbranded) devices with the proper parties, including the FDA, inhibited; and (v) not having the ability to look up reports concerning those devices on the FDA's website or other databases.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding customers having their service contracts and/or warranties with Intuitive voided or otherwise jeopardized and, on that basis, denies the allegations. SIS otherwise denies the remaining allegations.

83. While certain of the aforementioned categories of harm have injured Intuitive in a way that can be compensated in an amount to be determined at trial, much of it—such as the injury to Intuitive's reputation and customer relationships—is not readily calculable and may not be entirely redressed through monetary damages. Such irreparable harm can only be fully remedied through injunctive relief.

ANSWER: SIS denies the allegations.

COUNT ONE

(Unfair Competition and False Advertising – Lanham Act, 15 U.S.C. § 1125)

84. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

ANSWER: SIS incorporates by reference its responses to the previous and subsequent paragraphs as though fully set forth herein.

85. In its marketing materials and communications disseminated to potential and actual customers, SIS has made numerous false and misleading statements, including but not limited to the statements more specifically enumerated above that misrepresent: (i) the nature, efficacy, and/or safety of the service SIS coordinates (e.g., by referring to those services as mere "repairs" or similar terms); (ii) that "repaired" EndoWrists meet applicable quality and functional requirements; (iii) that devices "serviced" through SIS had been repaired to meet "original specifications" of EndoWrists and are

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safe to use; (iv) that SIS itself developed, has tested and conducts the "repairs;" (v) that the "repair" and/or resulting instruments do not require clearance by the FDA (and/or that SIS actually engaged in an independent or meaningful analysis of whether such clearance is necessary); (vi) that use of the service will result in substantial cost-savings; (vii) that use of the service does not carry any adverse financial, legal or other consequences (e.g., voiding Intuitive customers' warranties); (viii) that use limits built into EndoWrists are "arbitrary" or Intuitive otherwise is not trustworthy; and (ix) that SIS and/or the "repair" service is authorized, approved, or endorsed by Intuitive.

ANSWER: SIS admits that its "Summary of Quality and Reliability Measures" states that "The da Vinci® S/Si Instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures." SIS otherwise denies the allegations.

86. SIS's deceptive conduct also includes returning qualitatively different and inferior instruments to customers but passing off those products as genuine Intuitive EndoWrists. In that regard, "repaired" instruments still bear Intuitive's trademarks, including trademarks protected by incontestable federal registrations. The resulting confusion as to the source or affiliation of the "repaired" instruments is exacerbated by SIS's communications that also leverage Intuitive's trademarks and misinform customers that "a repaired EndoWrist® is not an alternative or replacement device," but rather "an original da Vinci® manufactured device that has been repaired to original specifications."

ANSWER: SIS admits that its instruments bear Intuitive's trademarks and that it states that "a repaired EndoWrist® is not an alternative or replacement device," and is "an original da Vinci® manufactured device that has been repaired to original specifications." SIS otherwise denies the allegations.

87. SIS's deceptive statements and conduct have deceived and confused, and/or have the capacity to deceive and confuse, a substantial segment of Intuitive's current and potential consumers.

ANSWER: SIS denies the allegations.

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88. SIS's deceptive statements and conduct are material and likely to influence consumer purchasing decisions.

ANSWER: SIS denies the allegations.

89. Both Intuitive's EndoWrists and SIS's services (and the "repaired" instruments) are advertised, offered for sale and sold in interstate commerce.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations that Intuitive's EndoWrists are advertised, offered for sale and sold in interstate commerce and, on that basis, denies the allegations. SIS admits that its services are advertised, offered for sale and sold in interstate commerce.

90. SIS's deceptive statements and conduct are willful and made with the knowledge that they are untruthful and/or unlawful.

ANSWER: SIS denies the allegations.

91. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

ANSWER: SIS denies the allegations.

COUNT TWO

(Unfair Competition Law – CA. Stat. § 17200)

92. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

ANSWER: SIS incorporates by reference its responses to the previous and subsequent paragraphs as though fully set forth herein.

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93. SIS's conduct detailed above constitutes unlawful, unfair and deceptive acts or practices in the conduct of trade or commerce.

ANSWER: SIS denies the allegations.

94. SIS willfully used or practiced these acts in violation of California's unfair competition statute, Section 17200, and SIS knew or should have known that its acts were unlawful and would damage Intuitive and injure consumers by its deception.

ANSWER: SIS denies the allegations.

95. SIS's conduct has resulted in substantial harm to competition.

ANSWER: SIS denies the allegations.

96. Intuitive, which has a principal place of business in California, has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations that Intuitive has a principal place of business in California and, on that basis, denies the allegations. SIS otherwise denies the allegations.

COUNT THREE

(False Advertising – CA. Stat. § 17500)

97. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

ANSWER: SIS incorporates by reference its responses to the previous and subsequent paragraphs as though fully set forth herein.

98. SIS intended for consumers in California to purchase EndoWrist "repairs" from it.

ANSWER: SIS admits that it intended for consumers in California to purchase refurbished EndoWrist from it.

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99. SIS's publicly disseminated marketing and advertising materials include numerous statements detailed above SIS knew or should have known through the exercise of reasonable care were both untrue and misleading.

ANSWER: SIS denies the allegations.

100. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

ANSWER: SIS denies the allegations.

COUNT FOUR

(Common Law Unfair Competition)

101. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

ANSWER: SIS incorporates by reference its responses to the previous and subsequent paragraphs as though fully set forth herein.

102. SIS is a competitor of Intuitive and has engaged in the above-detailed deceptive and fraudulent conduct with the intent to confuse and deceive the public into using its service and purchasing "repaired" EndoWrists.

ANSWER: SIS admits that it is a competitor of Intuitive with regard only to the sales of EndoWrists. SIS otherwise denies the allegations.

103. SIS's conduct has caused deception and confusion among consumers.

ANSWER: SIS denies the allegations.

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104. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

ANSWER: SIS denies the allegations.

COUNT FIVE

(Tortious Interference With Contract)

105. Intuitive incorporates by reference the allegations set forth in the previous and subsequent paragraphs of the Counterclaims.

ANSWER: SIS incorporates by reference its responses to the previous and subsequent paragraphs as though fully set forth herein.

106. At all relevant times, Intuitive has had contractual relationships with its customers, including through the SLSAs, which contain limitations concerning the modification or alteration of Intuitive EndoWrists. SIS was at all times aware of these contractual relationships and has undertaken intentional acts to disrupt them and/or induce Intuitive customers to breach them.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations that "[a]t all relevant times, Intuitive has had contractual relationships with its customers, including through the SLSAs, which contain limitations concerning the modification or alteration of Intuitive EndoWrists" and, on that basis, denies the allegations. SIS otherwise denies the allegations.

107. SIS's actions have resulted in actual breach or disruption of contractual relationships between Intuitive and its customers.

ANSWER: SIS lacks knowledge or information sufficient to form a belief as to the truth of the allegations and, on that basis, denies the allegations.

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108. There is no legal justification for SIS's actions, which have been motivated purely by its own greed and subjected Intuitive patients, Intuitive customers and Intuitive itself to substantial harm.

ANSWER: SIS denies the allegations.

109. Intuitive has suffered substantial harm, both monetary and irreparable, as a result of SIS's actions, and will continue to suffer such substantial harm unless those actions are restrained and enjoined by this Court.

ANSWER: SIS denies the allegations.

JURY TRIAL

110. Intuitive requests a jury trial as to all issues so triable.

ANSWER: SIS admits that Intuitive requests a jury trial as to all issues so triable.

PRAYER FOR RELIEF

111. Intuitive respectfully requests this Court enter judgment in favor of Intuitive and against SIS including an Order granting Intuitive the following relief:

a. Compensatory damages on all applicable causes of action alleged herein;

b. Actual costs, expenses and attorneys' fees incurred in this lawsuit;

c. All exemplary, enhanced and punitive damages;

d. Pre-judgment and post-judgment interest;

e. Preliminary and permanent injunctive relief; and

f. Such other and further relief as the Court shall deem just and proper.

ANSWER: SIS denies that Intuitive is entitled to any damages, costs, fees, interest, or injunctive relief.

GENERAL DENIAL

SIS denies each and every allegation of the Counterclaims which herein has been neither admitted nor controverted.

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Dated: January 10, 2022

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By: */s/ Joshua V. Van Hoven*

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CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2022, I caused a copy of the foregoing PLAINTIFF/COUNTERCLAIM DEFENDANT SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S ANSWER TO DEFENDANT/COUNTERCLAIM PLAINTIFF'S COUNTERCLAIMS to be served *via* electronic mail to counsel of record:

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